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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,422	07/24/2001	Jean Paul Remon	522-1741	4232

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Barnes & Thornburg
PO Box 2786
Chicago, IL 60690-2786

EXAMINER

JOYNES, ROBERT M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,422

Applicant(s)

REMON, JEAN PAUL

Examiner

Robert M. Joyner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,40,42-44 and 46-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-38, 41, 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,40,42-44 and 46-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>February 23, 2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination filed on February 23, 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39, 40, 42-44 and 46-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang (US 4590062) in combination with Khan et al. (US 5656296). Jang teaches a controlled release tablet formulation comprising an active agent and a combination of a hydrophobic cellulose derivative, a fatty acid material or a neutral lipid and a wax (Col. 3, lines 1-62). The components of the tablet are dry compressed together to produce a controlled release tablet. The active agent of the composition can be any substance when administered into the body of a human, animal, plant, soil and water is biologically active in a therapeutic sense (Col. 4, line 36 – Col. 6, line 19). The

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waxes of the composition have melting points from 50° to 100° C and are chosen from carnauba wax, spermaceti, beeswax, candelilla wax, esparto, and paraffin wax (Col. 3, lines 44-48; Col. 7, lines 27-41). The wax is present in the matrix composition up to 99 wt% (Col. 7, lines 27-41).

The teachings of Jang do not include a specific example of the embodiment of the instant claims. Jang does give concentration ranges of each of the components that do at least overlap with the concentration of the instant claims. Jang further does not teach the exact formulation for the active beads or particles.

Khan teaches active cores or particles that comprise a core of an active and a wax that is further coated to produce a sustained release formulation (Col. 2, lines 45-65). Khan recites various suitable pharmaceuticals that can be present in the drug cores (Col. 3, line 14 – Col. 4, line 50). The wax contained in the core can be natural or synthetic (Col. 4, line 51 – Col. 6, line 14).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of active agent as well as the amounts of wax present in the controlled release formulation of the Jang reference. While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Further, it would have been obvious to include as the

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active cores of Jang, the particles taught by the Khan reference. Finally, it is the position of the Examiner that the prior art teaches the waxes suitable for the instant claims and no criticality is seen in the new limitations of carbon chain length for the microcrystalline hydrocarbon waxes.

One of ordinary skill in the art would have been motivated to do this to prepare controlled release formulations for various active agents for humans, animals and plants, where in the amount of active agent can change the amount of wax and other excipients need for the controlled release system. Further, the amount of wax and additional ingredients will vary depending on the desired release rate or profile to be achieved. The expected result is a tablet formulation with an active agent and a wax component that achieves a controlled release profile.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed February 23, 2004 have been fully considered but they are not persuasive. Applicants argue that the prior art does not teach a solid shaped article comprising beads not powders, beads that also include a coating and wax in an amount that allows for release of the drug from the article.

First, the term bead does not connote any specific meaning without the inclusion of dimensions or units to define the size of the bead. While the references teach particles or powders and the instant claims are drawn to beads, no dimensions are

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included in the independent claims to distinguish over the prior art. Therefore, applicant's arguments to the contrary are unpersuasive.

Second, with regard to the coated beads, the Examiner relies on the secondary reference to teach coated cores or particles of active agents to be incorporated into tablet formulations. Khan teaches that once the coated cores are formed, they can be incorporated into a wide variety of sustained release compositions, including lozenges, tablets, chewy candy and the like (Col. 8, lines 18-39). Further, Khan also teaches that the term "coated cores" can include agglomerates gathered under one coating. Therefore, applicant's arguments that the prior art does not teach active cores or beads or agglomerate that are coated is unpersuasive.

Finally, applicant argues that the wax must be present in an amount that allows for release of the active agent. The range for the concentration of the wax in the primary reference (Jang) fully encompasses the range of the instant claims. While the reference does not teach the complete or narrowed concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Again, it is the position of the Examiner that would be obvious to include the coated beads/cores in the formulation of Jang wherein you would have a coated active core with a wax particles that are dry mixed and compressed into tablets. Whether you

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call the wax component particles or cushioning bead is no of consequence. You will still have a tablet comprising an active coated core with wax particle that were dry mixed and compressed to form tablets. Applicants have provided no superior or unexpected results over the prior art with the particular limitations recited in the instant claims. Absent a showing of unexpected results, applicants' instant claims are rendered obvious by the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571)

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272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes
Patent Examiner
Art Unit 1615

THURMAN K. PAGE
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